

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 09/893,604
Applicant : Robert A. HALLOWITZ et al.
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Examiner : J.S. PARKIN

Docket No. : BIOT111
Customer No. : 33449

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

DECLARATION OF JENNIFER A. GRAYSON UNDER 37 C.F.R. 1.132

Sir:

I, Jennifer A. Grayson, declare and state the following:

1. I am a citizen of the United States of America, residing at 1018 Eastbourne Ct Frederick MD 21704
2. I presently hold the position of Vice President of Regulatory Affairs at Bio-Tech Imaging, Inc.
3. I have been employed by Bio-Tech Imaging, Inc. since October 1999.
4. Micrococulture experiments were conducted by an independent clinical laboratory in September 1999- April 2000 using a ACTG/NIH consensus protocol. Mr. Bill Kabat, Laboratory Manager of the Infectious Disease Laboratory of the Children's Memorial Hospital in Chicago, IL had conducted micrococultures on patient samples shipped to him from Kaiser, San Francisco, CA. These were duplicate samples drawn at Kaiser where one tube of blood was sent to Mr. Kabat and the other tube was sent to our R & D lab in Albuquerque, NM and run using the BTI assay. Mr. Kabat's test results only showed the patient numbers/patients initials assigned by Kaiser.
5. Samples obtained from Kaiser, San Francisco, CA were analyzed using Bio-Tech Imaging assay described in the patent application entitled "Methods for characterizing the viral infectivity status of a host" in the R & D lab in Albuquerque, NM in September 1999- April 2000. The BTI test results was taken from a Statistical report compiled by Mike White of J.M. White Associates, Mount Vernon, WA on April 22, 2000 and are reported as a ratio as described in the above-mentioned patent application.

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6. I have compiled the data in the attached table. We had assigned our own BTI numbers and our data is documented using those numbers. In order to provide the information needed, I had to develop a correlation between the identification numbers that Mr. Kabat used and the BTI number. That correlation is included in this file. Using the correlation data I was able to match Mr. Kabat's test results with the BTI test results. I prepared a chart using the BTI test ratio results and the Kabat test results for 20 samples.

I hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements, and the like are so made, are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize that validity of the application or any patent issuing thereon.

Date: 11/13/03

Jennifer A. Grayson
Jennifer A. Grayson

BTI NUMBER	PATIENT NUMBER	BTI RATIO	QUANTITATIVE CULTURE RESULTS (RECIPROCAL ENDPOINT)
K266	2059C	19	negative
K267	2060	17	negative
K294	2061C	33	negative
K299	2064	36	negative
K302	2088	12	negative
K316	2062D	49	negative
K320	2109	24	negative
K321	2110	22	negative
K355	2134	11	negative
K372	2151	16	negative
K373	2149	30	negative
K375	2150	14	negative
K395	2173	18	negative
K412	2177	90	negative
K431	2173	18	negative
K435	2172	25	negative
K460	2206	13	negative
K461	2205	39	negative
K462	2207	30	negative
K484	2177B	76	negative

The data above demonstrates that BTI ratios (10 and above indicates infectivity) showed positive results when quantitative micro co-cultures were negative. Duplicate patient samples were split between BTI and scientist, Bill Kabat of Children Memorial Hospital in Chicago, IL.